WHAT IS CLAIMED IS:

1. A method for prophylactically sparing beta cell function in a mammal which has impaired glucose tolerance or early stage diabetes mellitus, comprising administering an orally effective dose of a pharmaceutical formulation comprising insulin at or shortly before bedtime.

2. A method for preventing beta cell death or dysfunction in a mammal which has impaired glucose tolerance or early stage diabetes mellitus, comprising administering an orally effective dose of a pharmaceutical formulation comprising insulin at or shortly before bedtime.

3. A method for long term protection of a mammal which has impaired glucose tolerance or early stage diabetes mellitus from developing overt diabetes, comprising administering an orally effective dose of a pharmaceutical formulation comprising insulin at or shortly before bedtime.

4. A method for delaying the onset of overt or insulin dependent diabetes in a mammal which has impaired glucose tolerance or early stage diabetes mellitus, comprising administering an orally effective dose of a pharmaceutical formulation comprising insulin at or shortly before bedtime.

5. The methods of claim 1, 2, 3 or 4, wherein the mammal is a rodent, dog, cat, sheep, pig, cow, horse or human.

6. The method of claim 5, wherein the mammal is a human.

7. The method of claim 1, 2, 3, 4, 5 or 6, wherein the oral pharmaceutical formulation is administered on a chronic basis.

8. The method of claim 1, 2, 3, 4, 5 or 6, wherein the oral pharmaceutical formulation is administered nightly for at least two weeks.

9. The method of claim 5, which provides a lowering of morning or fasting insulin levels of at least about 20%.

10. The method of claim 5, which achieves a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient, and which provides a ratio of portal vein to peripheral blood insulin concentration from about 2.5:1 to about 6:1.

11. The method of claim 5, wherein the oral dosage form of claim 3, wherein said dosage form is solid.

12. The method of any of the foregoing claims, wherein the dose of insulin contained in the dosage form is from about 50 Units to about 600 Units (from about 2 to about 23mg).

13. The method of any of the foregoing claims, wherein the dose of unmodified insulin is from about 100 Units (3.8 mg) to about 400 Units (15.3 mg) insulin.

14. The method of any of the foregoing claims, wherein the dose of unmodified insulin is from about 150 Units (5.75 mg) to about 300 Units (11.5 mg).

15. The method of any of the foregoing claims, wherein the dosage form(s) begin delivering insulin into the portal circulation (via absorption through the mucosa of the gastrointestinal tract) to achieve peak levels within about 30 minutes or less.

16. A method of treating mammals having impaired glucose tolerance or early stage diabetes mellitus, comprising,

orally administering insulin at or shortly before bedtime to mammals having impaired glucose tolerance or early stage diabetes mellitus such that a statistically significant decrease in C-peptide levels from a mean baseline level is achieved in said mammals when said C-peptide level is measured about 8 hours after said oral administration of insulin.

17. The method of claim 16, wherein said C-peptide levels when measured are decreased by a mean of about 24%.

18. The method of claim 16 or 17, wherein plasma insulin levels are reduced by a statistically significant degree from baseline when measured about 8 hours after said oral administration of insulin.

19. The method of claim 18, wherein said plasma insulin levels are reduced by a mean of about 33% from baseline when measured about 8 hours after said oral administration of insulin.

20. The method of claim 16, 18 or 19, wherein blood glucose levels are reduced by a statistically insignificant degree from baseline when measured about 8 hours after said oral administration of insulin.

21. The method of claim 20, wherein said blood glucose levels are reduced by a mean of about 6% from baseline when measured about 8 hours after said oral administration of insulin.

22. The method of any of claims 16-21, wherein said oral administration of insulin comprises a dose of from about 200 to about 400 units of insulin and an effective amount of a pharmaceutically acceptable delivery agent which facilitates absorption of said insulin from the gastrointestinal tract of said mammals.

23. The method of claim 22, wherein said pharmaceutically acceptable delivery agent comprises 4-CNAB.

24. The method of claim 22, wherein said pharmaceutically acceptable delivery agent comprises about 300 mg 4-CNAB.

25. The method of any of claims 16-22, wherein said insulin is an unmodified insulin.

26. A method of prolonging the effect of an oral administration of an unmodified insulin in order to treat diabetic patients, comprising orally administering at bedtime a dosage form comprising a orally therapeutically effective amount of unmodified insulin to a diabetic patient which provides an insulin t_{max} at a time point from about 0.1 to about 1.5 hours after said oral administration, such that a statistically significant decrease in C-peptide levels from baseline is achieved in said patients when said C-peptide level is measured about 8 hours after said oral administration of insulin.

27. A method of prolonging the effect of an oral administration of an unmodified insulin in order to treat mammals who have impaired glucose tolerance, comprising orally administering at bedtime a dosage form comprising a orally therapeutically effective amount of unmodified insulin to a diabetic patient which provides an insulin t_{max} at a time point from about 0.1 to about 1.5 hours after said oral administration, such that a statistically significant decrease in C-peptide levels from baseline is achieved in said patients when said C-peptide level is measured about 8 hours after said oral administration of insulin.

28. A method of prolonging the effect of an oral administration of an unmodified insulin in order to treat diabetic patents, comprising orally administering at bedtime a dosage form comprising an orally therapeutically effective amount of unmodified insulin to a diabetic patient which provides an insulin t_{max} at a time point from about 0.1 to about 1.5 hours after said oral administration, such that plasma insulin levels are reduced by a statistically significant degree from baseline when measured about 8 hours after said oral administration of insulin.

29. A method of prolonging the effect of an oral administration of an unmodified insulin in order to treat mammals who have impaired glucose tolerance, comprising orally administering at bedtime a dosage form comprising an orally therapeutically effective amount of unmodified insulin to a diabetic patient which provides an insulin t_{max} at a time point from about 0.1 to about 1.5 hours after said oral administration, such that plasma insulin levels are reduced by a statistically significant degree from baseline when measured about 8 hours after said oral administration of insulin.

30. A method of prolonging the effect of an administration of oral insulin for a time period longer than the time period that the insulin can be measured in the blood stream, comprising orally administering at or shortly before bedtime a dosage form comprising an orally therapeutically effective amount of insulin to a diabetic patient, such that:

(i) the blood glucose level of the patient when measured about 8 hours after said oral administration is not statistically significantly changed from baseline levels; or

(ii) endogenous insulin production of the patient is lowered by a statistically significant degree as compared to baseline insulin levels when measured about 8 hours after said oral administration, as evidenced by reduced C-peptide levels; or

(iii) plasma insulin levels of the patient are lowered by a statistically significant degree as compared to baseline plasma insulin levels when measured about 8 hours after said oral administration; or

(iv) any combination of (i) – (iii) above.

31. The method of any of claims 27-30, wherein said oral administration of insulin comprises a dose of from about 200 to about 400 units of insulin and an effective amount of a pharmaceutically acceptable delivery agent which facilitates absorption of said insulin from the gastrointestinal tract.

32. The method of claim 31, wherein said pharmaceutically acceptable delivery agent comprises 4-CNAB.

33. The method of claim 31, wherein said pharmaceutically acceptable delivery agent comprises about 300 mg 4-CNAB.

34. The method of any of claims 27-30, wherein said insulin is an unmodified insulin.

35. The method of claim 30, wherein said C-peptide levels are decreased by a mean of about 24% when measured about 8 hours after said oral administration of insulin.

36. The method of claim 30, wherein said plasma insulin levels are reduced by a mean of about 33% when measured about 8 hours after said oral administration of insulin.

37. The method of claim 30, wherein said blood glucose levels are reduced by a mean of about 6% when measured about 8 hours after said oral administration of insulin.

38. The method of any of claims 16-25, 27 and 29, wherein said mammal is a human.

39. The method of any of claims 26, 28 and 30-37, wherein said diabetic patient is a human.